DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-942/S-004

Hoffmann-LaRoche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Margaret J. Jack
Program Director

Dear Ms. Jack:

Please refer to your supplemental new drug application dated May 22, 2000, received May 23, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Versed (midazolam hydrochloride) Syrup.

We acknowledge receipt of your submissions dated September 12 and December 21, 2000, and February 20, 2001. Your submission of December 21, 2000, constituted a complete response to our September 1, 2000, action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the package insert to include interactions between midazolam and saquinavir.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling text with the minor editorial revisions listed below.

1. In Table 1., replace “Number of subjects/age” heading with “Number of Subjects/age group.”

2. In Table 2., Adult Doses Studied column, saquinavir row, replace 120 mg tid with1200 mg tid.

3. In Table 4., delete the row regarding magnesium hydroxide.

The supplemental application is approved effective on the date of this letter, with the changes described above.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert submitted May 22, 2000). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-942/S-004." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research